Evaluating Clinical Study Deficiencies Found During Inspection Using AI

Jerry L. Chapman

Senior GMP Quality Expert, Redica Systems

Our Company

REDICA Systems

Formerly Govzilla

An Essential Tool for Regulatory Intelligence & Compliance

Our extensive data feeds, proprietary site and inspector profiles, push-button reports, and white-glove client service transform the way our users discover, decide, and act on regulatory intelligence in the GMP, GCP, and GLP worlds.

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Agenda

- Importance and challenges of human clinical studies
- Inspection landscape: deficiency statistics
- Data sources and evaluation using AI Tools
- What we can learn from US FDA CI Warning Letters
- A deeper dive into 483 data and some surprises
- Summary and Conclusions

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Importance of Human Clinical Studies

- New treatments for diseases to improve individual and public health.

- New ways to detect, diagnose, and reduce the chance of developing the disease.

- What does and doesn’t work in humans that cannot be learned in the laboratory or in animals.

- **Data generated is a key part of FDA approval of the drug or device**

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Some Challenges of Conducting Human Clinical Studies

- Selection of patient population
- Coordinating decentralized trials
- The use of real-world data/real-world evidence
- **Investigator selection**
- **Changing in clinical trial expectations**
- **Selection and oversight of vendors**
- **Keeping up-to-date with guidance and inspection approaches**

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Challenges: Keeping Current on Agency Inspection Guidance

FDA BIMO Inspection Guide 7348.810: Sponsors and CMOs, Sept. 2021

Increased emphasis (among others) on:

- Selecting and monitoring clinical investigators – their compliance history
- Selecting and making changes in the Principal Investigator
- Risk mitigation if there are issues – or to prevent issues

Issues resulting from selection and monitoring of CIs and PIs can become agency inspection findings

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The GCP Inspection Landscape: Prioritizing which data sets to examine

BIMO Inspections by type*

	CI	IRB	S/CRO/SI
2021	437	29	84
2020	544	77	84
2019	779	140	127
2018	904	163	175
2017	701	124	106
2016	775	124	112

Looking at these clinical study inspection categories, CI is usually about 75% of inspections; adding IRB, the two together are about 87% of inspections

We chose to look at CI and IRB, beginning with CI

*Omitting GLP, BA/BE, PADE & REMS inspections; only focusing on sponsors, investigators, and IRB; Source: FDA.gov

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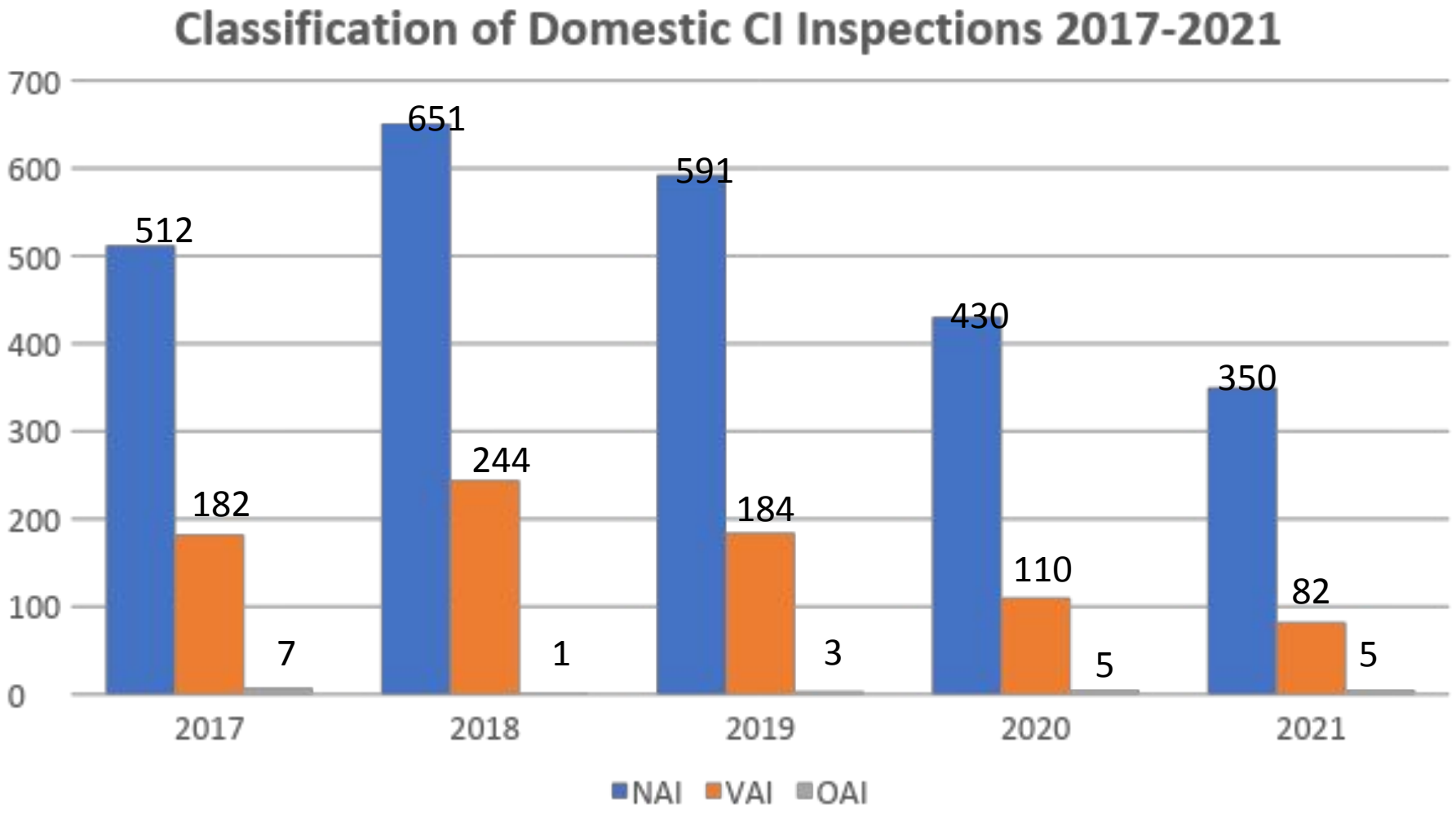
The CI Inspection Outcomes



Key takeaway: About 1 in 3 FDA BIMO inspections resulted in a 483; fewer than 1 in 100 resulted in a warning letter

*Source: FDA.gov

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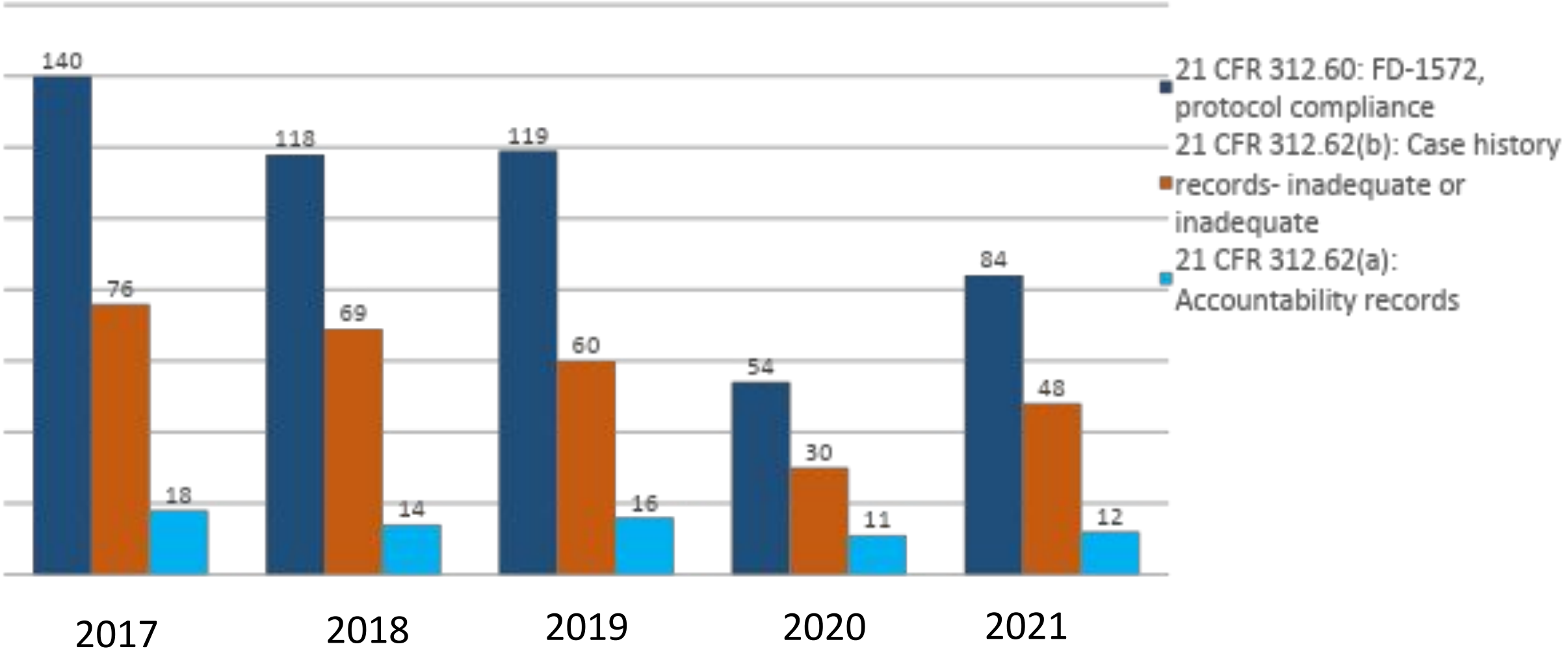
The Top 3 Published Agency Inspection Findings on 483s



Always the same. More detail is needed. Follow me as I walk through how mined the data to get more detail.

Source: FDA.gov

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Data Sources, How We Organize and Use Them

Data Sources

- All data are from PUBLIC sources
- FDA Inspections databases (CLIIL and FACTS) – Dec 8, 2018
- FDA CFR Citations database
- Warning Letters from FDA.gov
- 50,000+ 483s, responses and EIRs (FOIA and FDA.gov)
- FDA registration databases (e.g., GDUFA)
- FDA 21 CFR 211 catalogue (Cornell University)
- Team of data scientists/engineers
- Experts - Jerry Chapman (GMP), Barbara Unger (GMP), Jane Wastl (GMP), Mark Agostino (med devices), Fran Lambetecchio (GVP/GCP), others

Site Tags

- CDER
  - Rx manufacturing (API and FDF)
  - Over-the-Counter (OTC)
  - Other CDER (e.g., unapproved drugs)
  - GCP (Clinical Investigators, IRBs, Sponsors)
  - Compounding Pharmacies
- CBER
- CDRH
- MHRA
- Health Canada
- etc.

How do we use the data?

- Investigator profiles
- CMO/CRO due diligence
- Vendor selection
- Inspection preparation
- Keeping PQS up to date
- Tracking changes to authoritative sources
- Tracking and trending inspection observations
- Finding observations and citations “hiding in plain sight”
- Tip of the iceberg…

Key takeaway: Redica Systems has more publicly-available documents in these areas than any non-governmental entity

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How Do We Analyze These Data Sets: Using AI Tools

- Redica Systems has created AI tools – “expert models” – that allow deep and rapid analysis of compliance and other data sets.
- Created using Machine Learning, Natural Language Processing (NLP) and other AI tools, used to analyze FDA warning letters, 483s, and other documents the way an expert would.
- To begin to train the AI algorithm and prepare the documents for examination, there are initial, important steps that must be taken
- Natural Language Processing (NLP) tools, including *scanning, parsing, cleaning, tokenizing, POS tagging, stemming, etc.*

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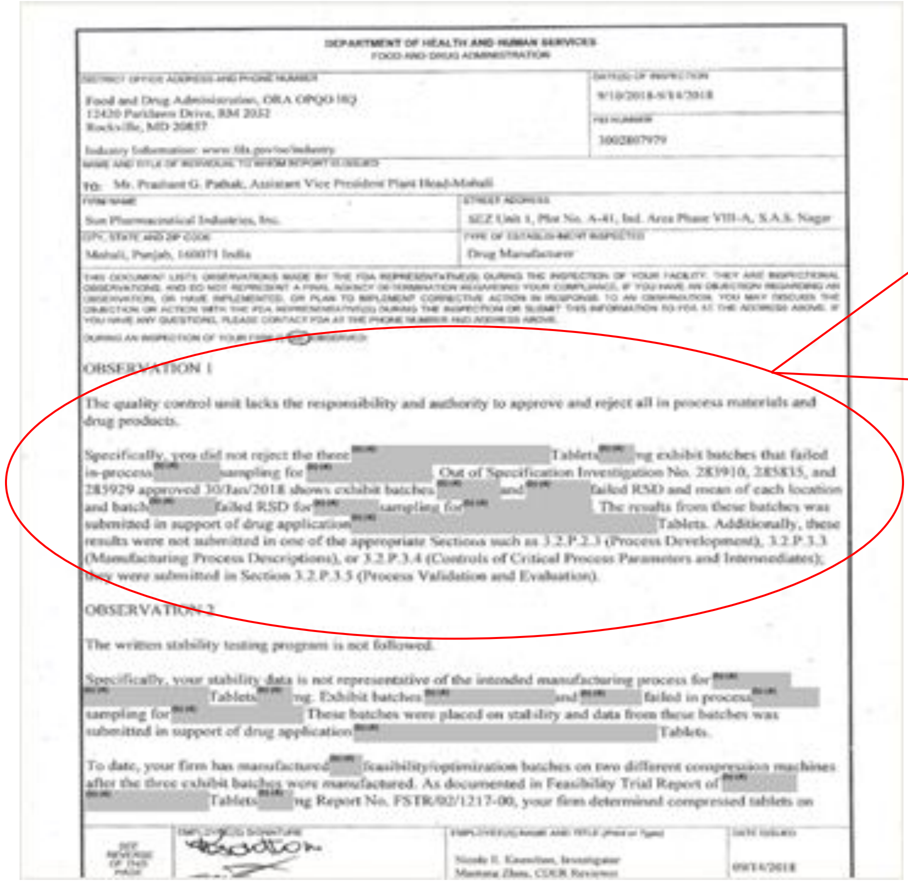
Making Picture File Documents Searchable and Machine Readable

Processed >50,000 483s, 483R, and EIRs



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration, ORA OPQO HQ
12420 Parklawn Drive, RM 2032
Rockville, MD 20857

Industry Information: www.fda.gov/oc/industry

9/10/2018-9/14/2018

3002807979

TO: Mr. Prashant G. Pathak, Assistant Vice President Plant Head-Mohali

Sun Pharmaceutical Industries, Inc.

SEZ Unit 1, Plot No. A-41, Ind. Area Phase VIII-A, S.A.S. Nagar

Mohali, Punjab, 160071 India

Drug Manufacturer

OBSERVATION 1

The quality control unit lacks the responsibility and authority to approve and reject all in process materials and drug products.

Specifically, you did not reject the three [redacted] Tablets [redacted] mg exhibit batches that failed in-process [redacted] sampling for [redacted]. Out of Specification Investigation No. 283910, 285835, and 285929 approved 30/Jan/2018 shows exhibit batches [redacted] and [redacted] failed RSD and mean of each location and batch [redacted] failed RSD for [redacted] sampling for [redacted]. The results from these batches was submitted in support of drug application [redacted] Tablets. Additionally, these results were not submitted in one of the appropriate Sections such as 3.2.P.2.3 (Process Development), 3.2.P.3.3 (Manufacturing Process Descriptions), or 3.2.P.3.4 (Controls of Critical Process Parameters and Intermediates); they were submitted in Section 3.2.P.3.5 (Process Validation and Evaluation).

OBSERVATION 2

The written stability testing program is not followed.

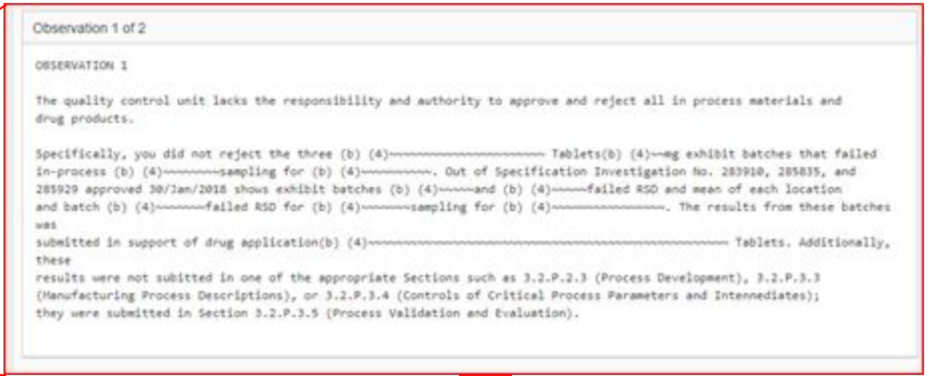
Specifically, your stability data is not representative of the intended manufacturing process for [redacted] Tablets [redacted] mg. Exhibit batches [redacted] and [redacted] failed in process [redacted] sampling for [redacted]. These batches were placed on stability and data from these batches was submitted in support of drug application [redacted] Tablets.

To date, your firm has manufactured [redacted] feasibility/optimization batches on two different compression machines after the three exhibit batches were manufactured. As documented in Feasibility Trial Report of [redacted] Tablets [redacted] mg Report No. FSTR/02/1217-00, your firm determined compressed tablets on

Nicole E. Knowlton, Investigator
Mastura Zhou, CDER Reviewer

09/14/2018

Clean Observation Text: OCR, Proofing, Retyping



Observation 1 of 2

OBSERVATION 1

The quality control unit lacks the responsibility and authority to approve and reject all in process materials and
drug products.

Specifically, you did not reject the three (b) (4)~~~~~~~~~~~~~~~~~~~ Tablets(b) (4)~~mg exhibit batches that failed
in-process (b) (4)~~~~~~~sampling for (b) (4)~~~~~~~~. Out of Specification Investigation No. 283910, 285835, and
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Parse "main topic" of Observation

Failure to properly determine subject eligibility in that subjects have been accepted with bogus names, phone numbers, and Social Security Numbers.

Documents must be machine readable – i.e., not picture files – to be analyzed.

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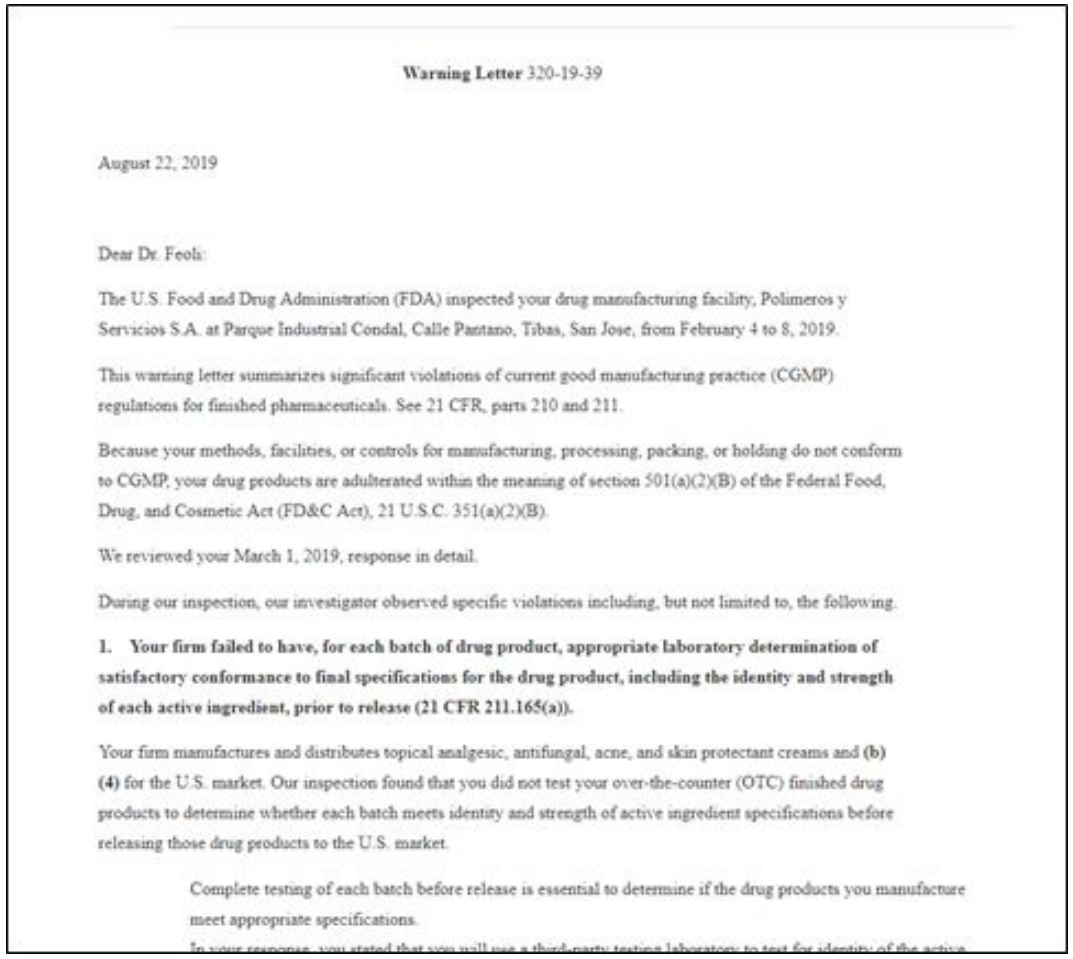
Natural Language Processing: Text Parsing



Warning Letter 320-19-39

August 22, 2019

Dear Dr. Feola:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Polimeros y Servicios S.A. at Parque Industrial Condal, Calle Pantano, Tibas, San Jose, from February 4 to 8, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your March 1, 2019, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).

Your firm manufactures and distributes topical analgesic, antifungal, acne, and skin protectant creams and **(b) (4)** for the U.S. market. Our inspection found that you did not test your over-the-counter (OTC) finished drug products to determine whether each batch meets identity and strength of active ingredient specifications before releasing those drug products to the U.S. market.

Complete testing of each batch before release is essential to determine if the drug products you manufacture meet appropriate specifications.

In your response, you stated that you will use a third-party testing laboratory to test for identity of the active

Drug GMP Warning Letter "parts"

- Name
- Recipient
- Issuing office
- Introduction
- **Deficiency title 1 with CFR reference**
- Deficiency description 1
- Deficiency action or compliance description 1
- Deficiency feedback 1
- **Deficiency title 2 with CFR reference**
- Deficiency description 2
- Deficiency action or compliance description 2
- Deficiency feedback 2
- **Deficiency title n with CFR reference**
- Deficiency description n
- Deficiency action or compliance description n

Key takeaway: Documents must be parsed into logical sections to allow analysis of the appropriate data sets.

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Natural Language Processing: Text Parsing

The “deficiency title” sections include the CFR reference, which is high-level and general.

1. You failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60]. *As a clinical investigator, you are required to ensure that your clinical studies are conducted in accordance with the investigational plan…*

Specifically…

It is the “specifically” or “for example” text in the “deficiency description” that contains rich content and allows us to drill down and get more granular regarding deficiencies.

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Deficiency Title and Deficiency Text

You failed to ensure that the investigation was conducted according to the investigational plan [21 CFR § 312.60]. Specifically,

—The following subjects were enrolled, despite meeting this exclusion criterion.

—You failed to follow the protocol-specified recommended guidelines…

—…administered study vaccine to Subject **(b)(6)** that was stored in a refrigerator that had a temperature excursion to 9.1ºC for at least 30 minutes…

—Protocol (b)(4) required you to perform certain procedures, such as chest X-rays, at specific times. You failed to adhere to these requirements

—You failed to follow the protocol for subject eligibility

—The investigational plan for Protocol (b)(4) required that you perform the (b)(4) approximately 24 hours after dosing. You failed to adhere to these requirements

NOTE: The seriousness of a 483 or warning letter cannot be measured by the number of citations/observations

—You failed to conduct TSH and AFP laboratory tests at required time intervals

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Building and Applying the Models

- Experts create n-grams for each category and subcategory; also, TurboEIR 483 text
- Expert models for human drugs and medical devices are built, tested, and deployed
- Models differ due to document parsing, n-grams, TurboEIR text, and subject matter experts evaluating them
- Other expert models, e.g. for **GCP|CI, GCP|IRB, APIs, human cell and tissue/GTP**, have been built and are in the testing phase
- The models are organized differently to match the topic.
- *How is the GCP model organized?*

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GCP Classification Model – IRB and Clinical Investigator (CI) **DRAFT**

IRB: Informed Consent

- **General Requirements** (3 sub-categories)
- **Exception from informed consent requirements for emergency research**
- **Documentation of informed consent** (2 sub-categories)

IRB: General Provisions

- **Welfare of human subjects**
- **Emergency Use Reporting**

IRB: Safeguards for Children

- **IRB Duties**
- **Clinical investigations not involving greater than minimal risk**
- **Clinical investigations involving greater than minimal risk** (2 sub-categories)
- **Not otherwise approvable (**2 sub-categories
- **Parent or guardian permission and child assent**
- **Wards**

IRB: Org. and Personnel

- **Registration** (4 sub-categories)
- **IRB membership** (7 sub-categories)

IRB: Records and Reports

- **IRB records** (4 sub-categories)

IRB: Functions and Operations

- **IRB functions and operations** (9 sub-categories)
- **Review of research** (6 sub-categories)
- **Expedited review procedures for certain kinds of research involving no more than minimal risk**
- **Expedited review procedures for minor changes in approved research**
- **Criteria for IRB approval of research** (6 subs)
- **Review by institution**
- **Suspension or termination of IRB approval of research**
- **Cooperative research**

IRB/CI: Data Integrity

- **Accurate**
- **Attributable** (3 sub-categories)
- **Backup and Archival**
- **Contemporaneous**
- **Data Destruction**
- **Data Manipulation**
- **Legible**
- **Original Data**
- **Paper Record Controls**
- **System Controls**
- **Testing into Compliance**

CI: Responsibilities of Sponsors & Investigators

- **General** (conducting study, protecting subjects, controlling drugs under investigation, obtaining informed consent)
- **Conducted according to investigational plan** (6 sub-categories)
- **Investigator record keeping and record retention** (3 sub-categories)
- **Investigator reports** (4 sub-categories)
- **Assurance of IRB review** (3 sub-categories)
- **Inspection of investigator's records and reports** (1 sub-category)
- **Handling of controlled substances**

CI: Informed Consent

- **General Requirements** (coercion, exculpatory language, obtaining, understandable language)
- **Exception from general requirements**
- **Exceptions from informed consent for emergency research**
- **Elements of informed consent** (3 sub-categories)
- **Documentation of informed consent (**3 sub-categories)

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Evaluating FDA Enforcement Actions: CI Warning Letters

Our Warning Letter CI data set:

FDA Warning Letters:

- 25 CI warning letters issued in the last six years

Following are the results of the application of the model

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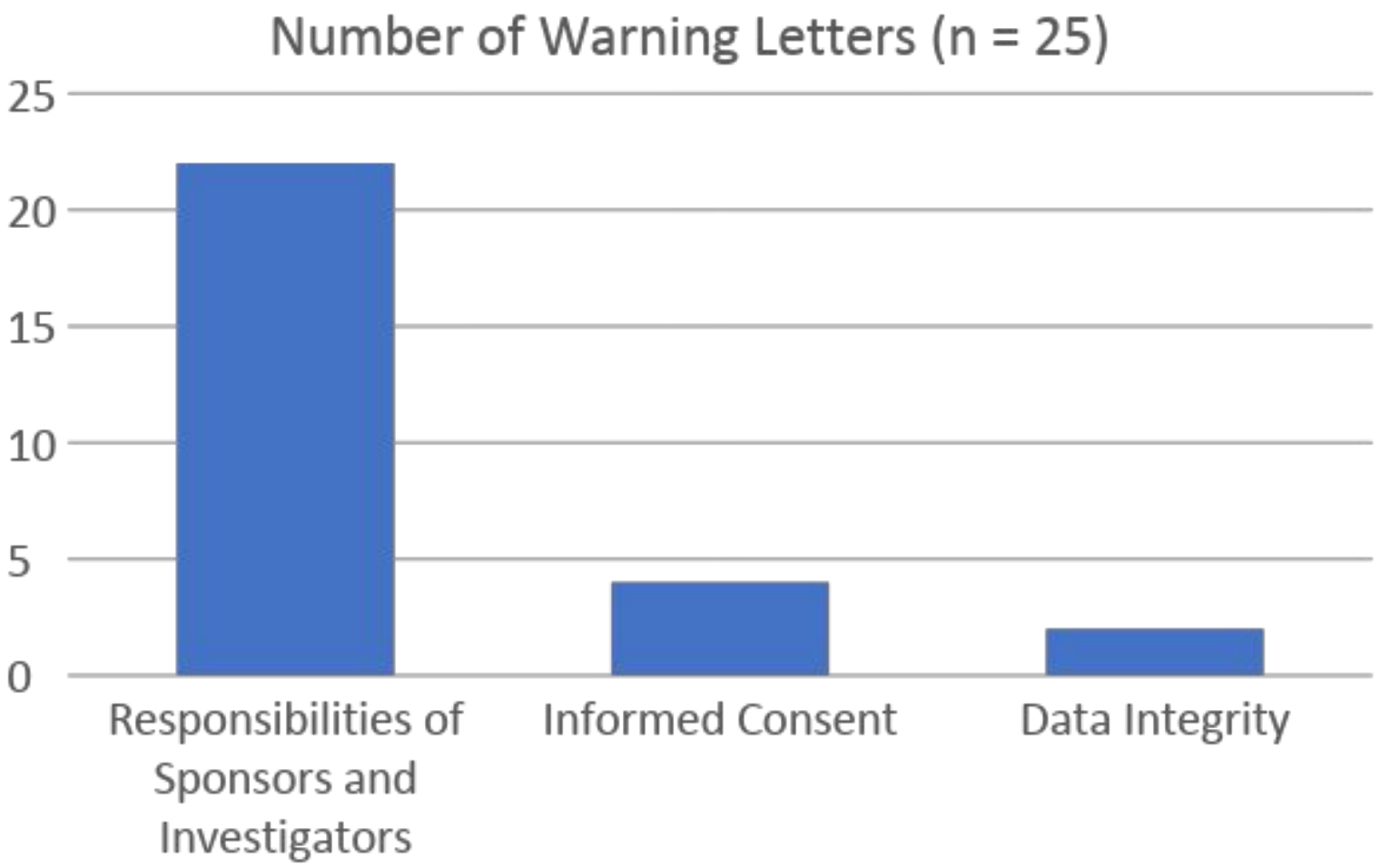
FDA Warning Letter Analysis



The number of warning letters out of 25 tagged for language indicating issues in the three Level 1 categories in our model.

Key takeaway: As perennially reported, responsibilities of investigators is the most common high-level finding

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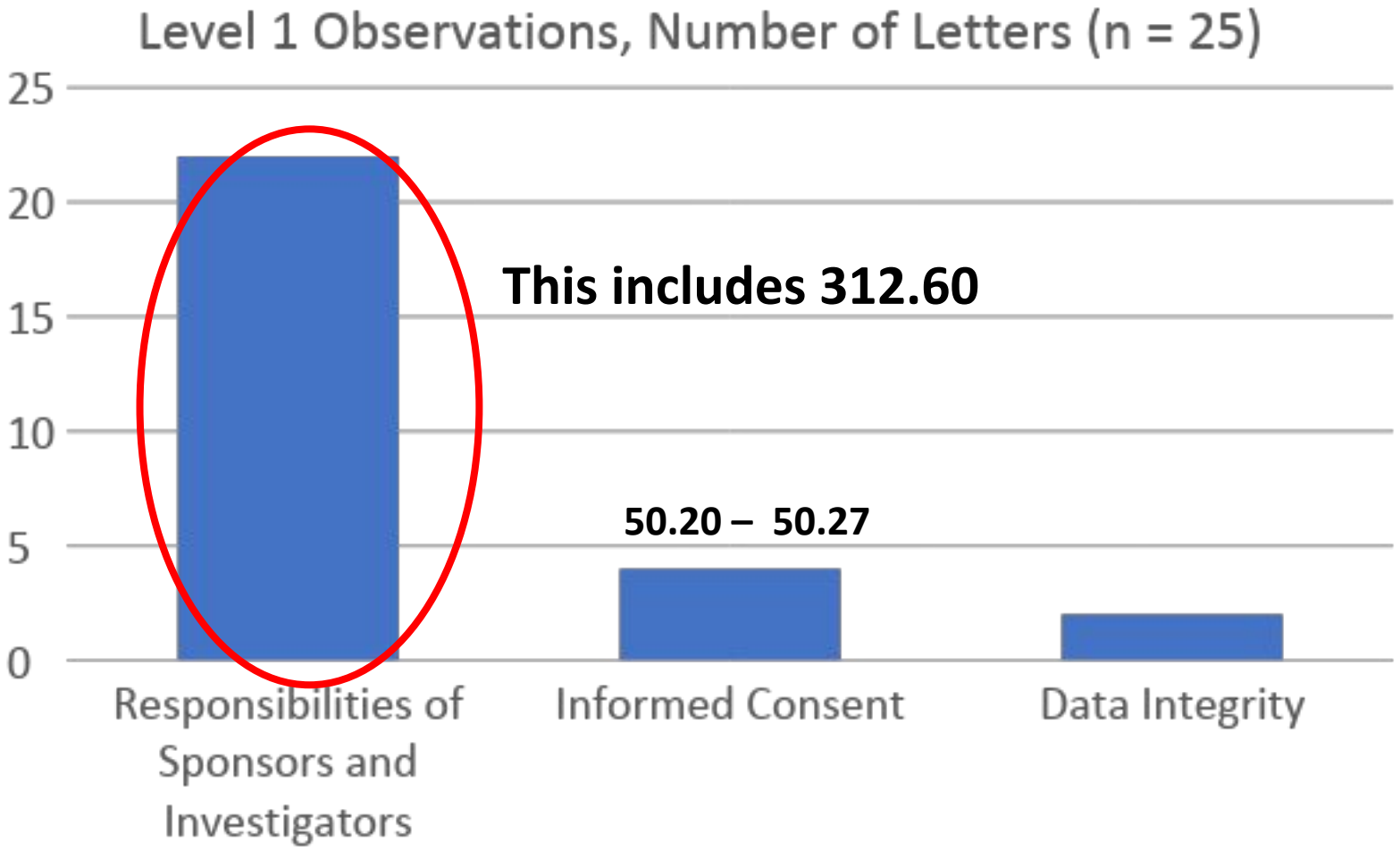
FDA Warning Letter Analysis



The number of warning letters out of 25 tagged for language indicating issues in the three Level 1 categories in our model.

Let's look more closely at the "responsibilities of the investigator" category.

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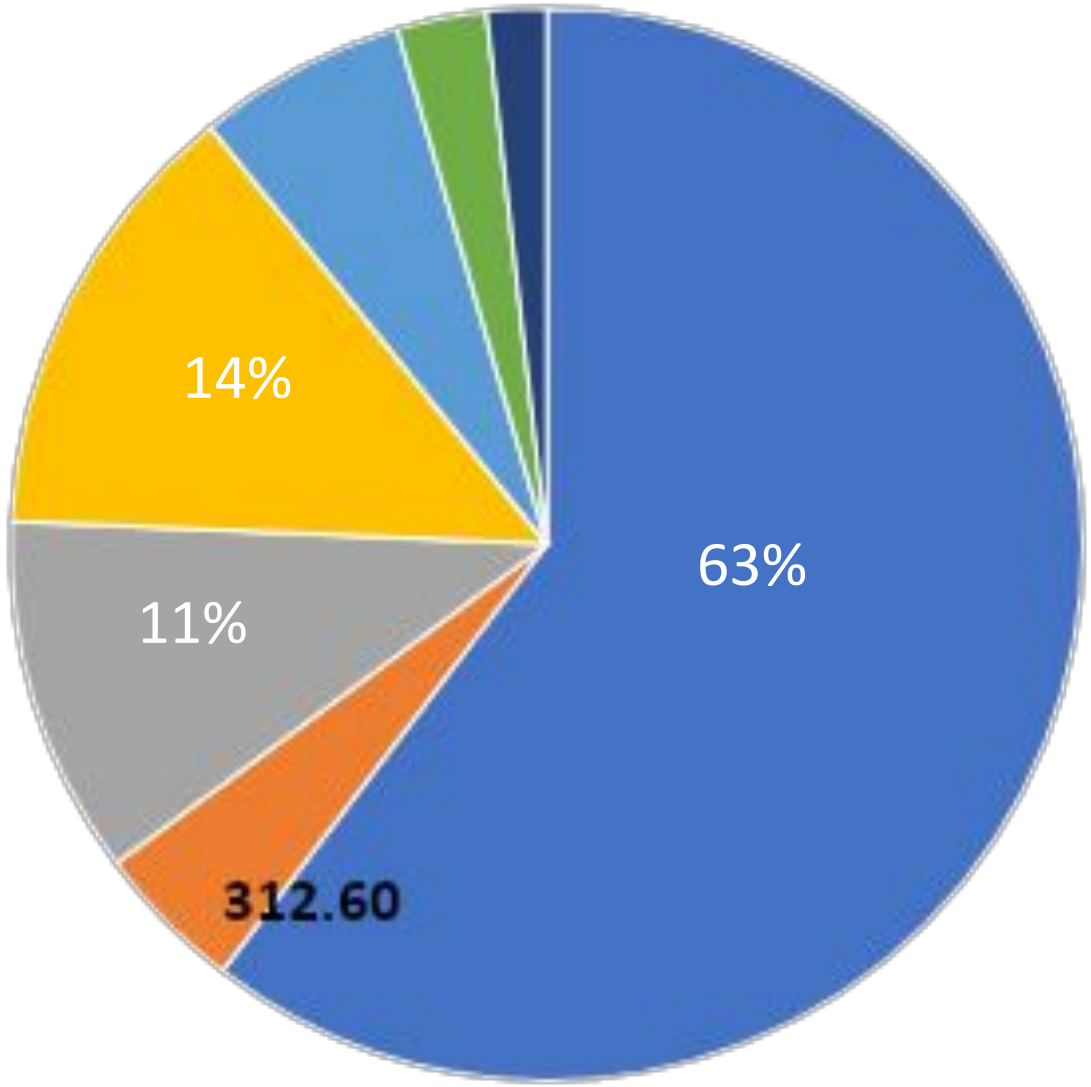
Warning Letters: Responsibilities of Investigators Broken Down

312.61-70



- General Responsibilities - Conducted According to Investigational Plan
- General Responsibilities - 3 other sub-categories
- Assurance of IRB Review
- Investigator Recordkeeping and Record Retention - Case Histories
- Investigator Recordkeeping and Record Retention - Disposition of Drug During Study
- Investigator Recordkeeping and Record Retention - subcategory
- Investigator Reports - Financial Disclosure reports

What do the regulations say in 21 CFR 312.60?

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FDA Warning Letter Analysis: 21 CFR 312.60 – The Most Cited

§ 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is **conducted according to the signed investigator statement, the investigational plan, and applicable regulations**; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation. An investigator shall, in accordance with the provisions of part 50 of this chapter, **obtain the informed consent** of each human subject to whom the drug is administered, except as provided in §§ 50.23 or 50.24 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

FDA inspection citations:

#1: FD-1572, protocol compliance: An investigation was not conducted in accordance with the [signed statement of investigator] [investigational plan]. Specifically,***

#8: Informed consent: Failure to obtain informed consent in accordance with 21 CFR Part 50 from each human subject prior to [drug administration] [conducting study-related tests] . Specifically,*** [Also cited under 50.20 – 50.27]

Wouldn't it be nice to know what aspects of protocol compliance are being found deficient?

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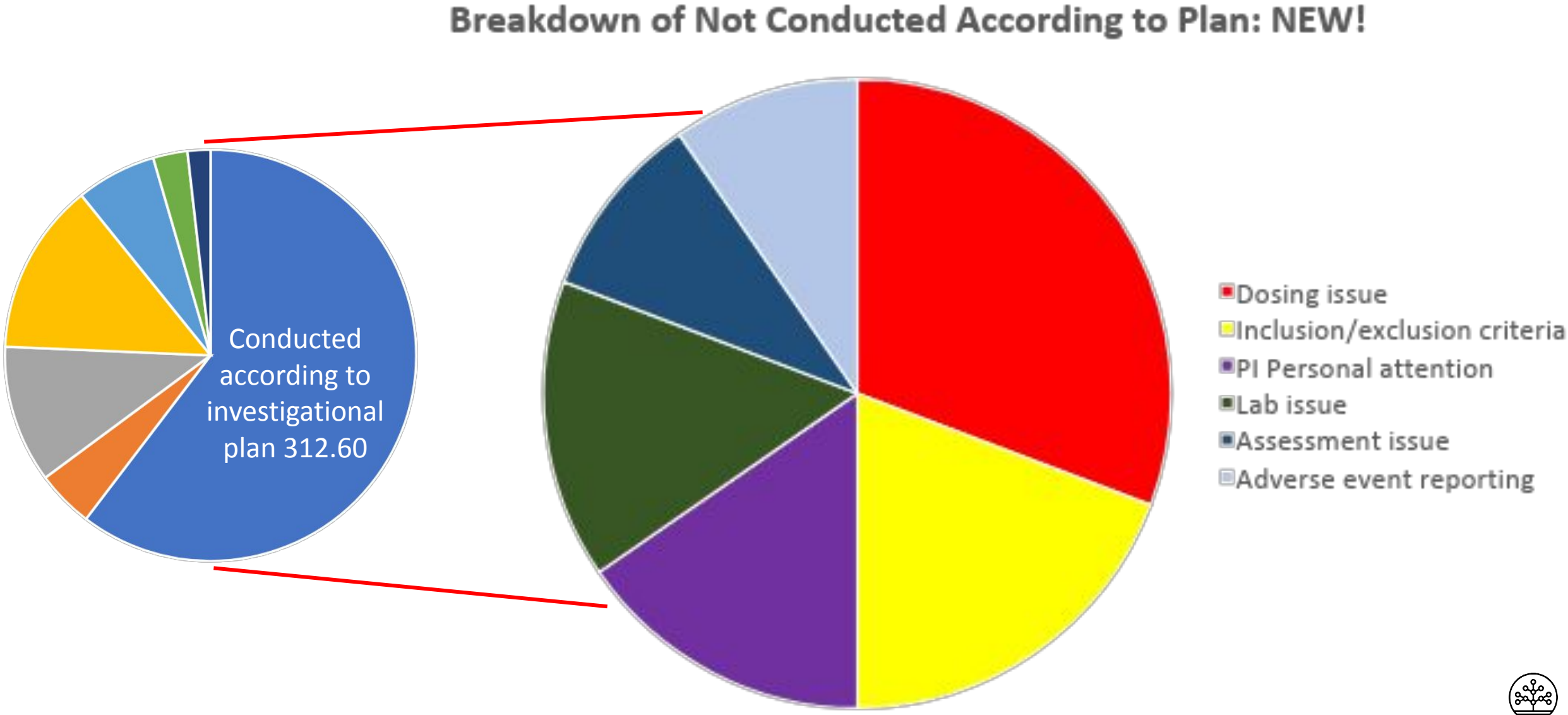
Warning Letters: *Conducted According to Plan (BETA)*



Key takeaway: This is an actual useful breakdown of 312.60 citations, which are specific protocol violations.

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Evaluating FDA Enforcement Actions: Warning Letters and 483s

Our 483 CI data set:

FDA 483s – a much larger data set that lends itself to deeper analysis

- 1,213 483s issued to Clinical Investigators over the last 20 years
- 6756 pages; 2,778,719 words*

Following are the results of the application of our model to this data set.

*When pasted into Word, 11-point font

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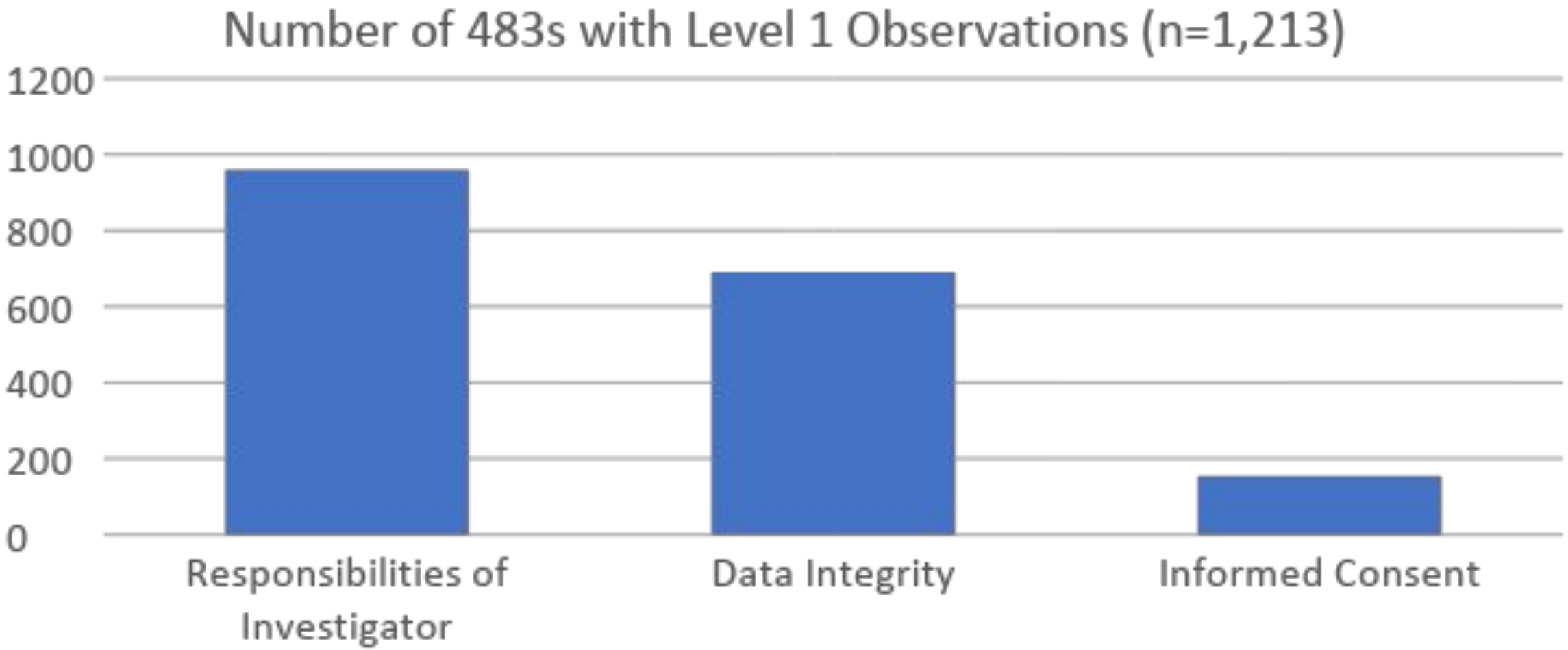
FDA 483 Analysis



Key takeaway: Issues around data integrity are far more common in 483s than in warning letters.

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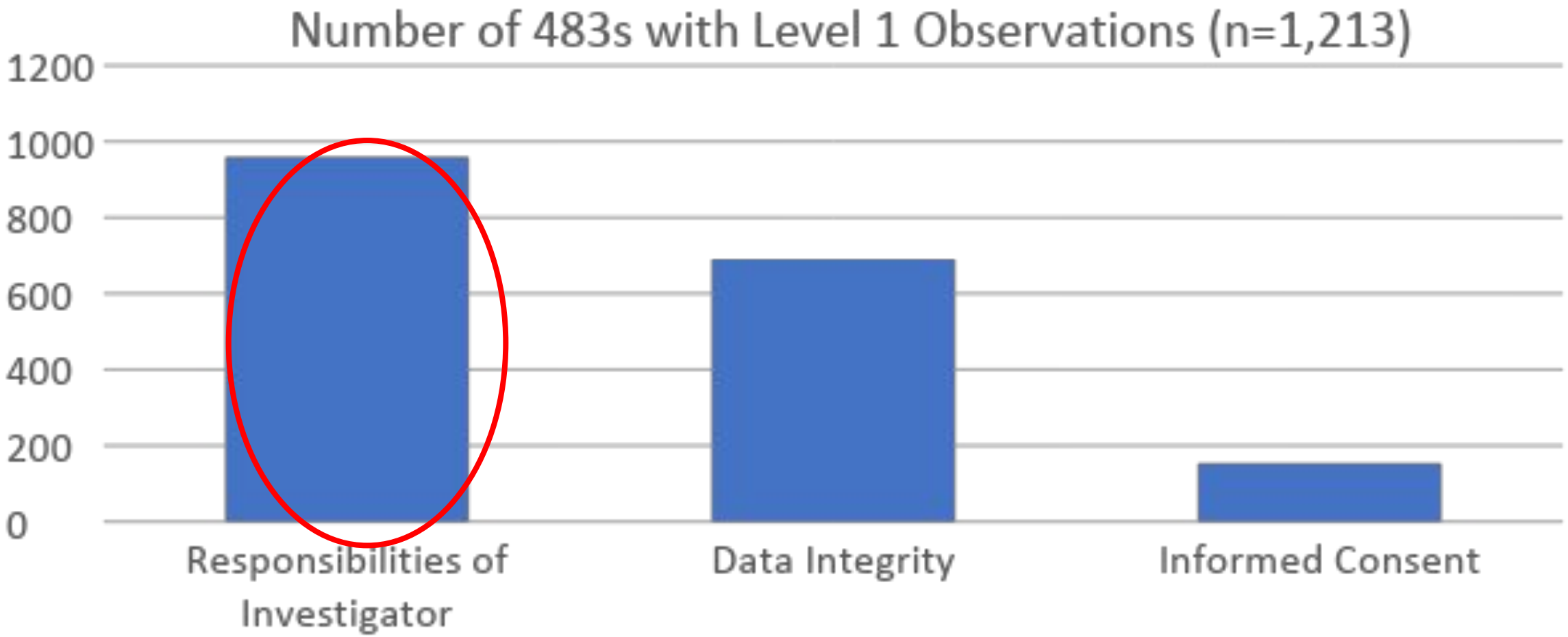
FDA 483 Analysis



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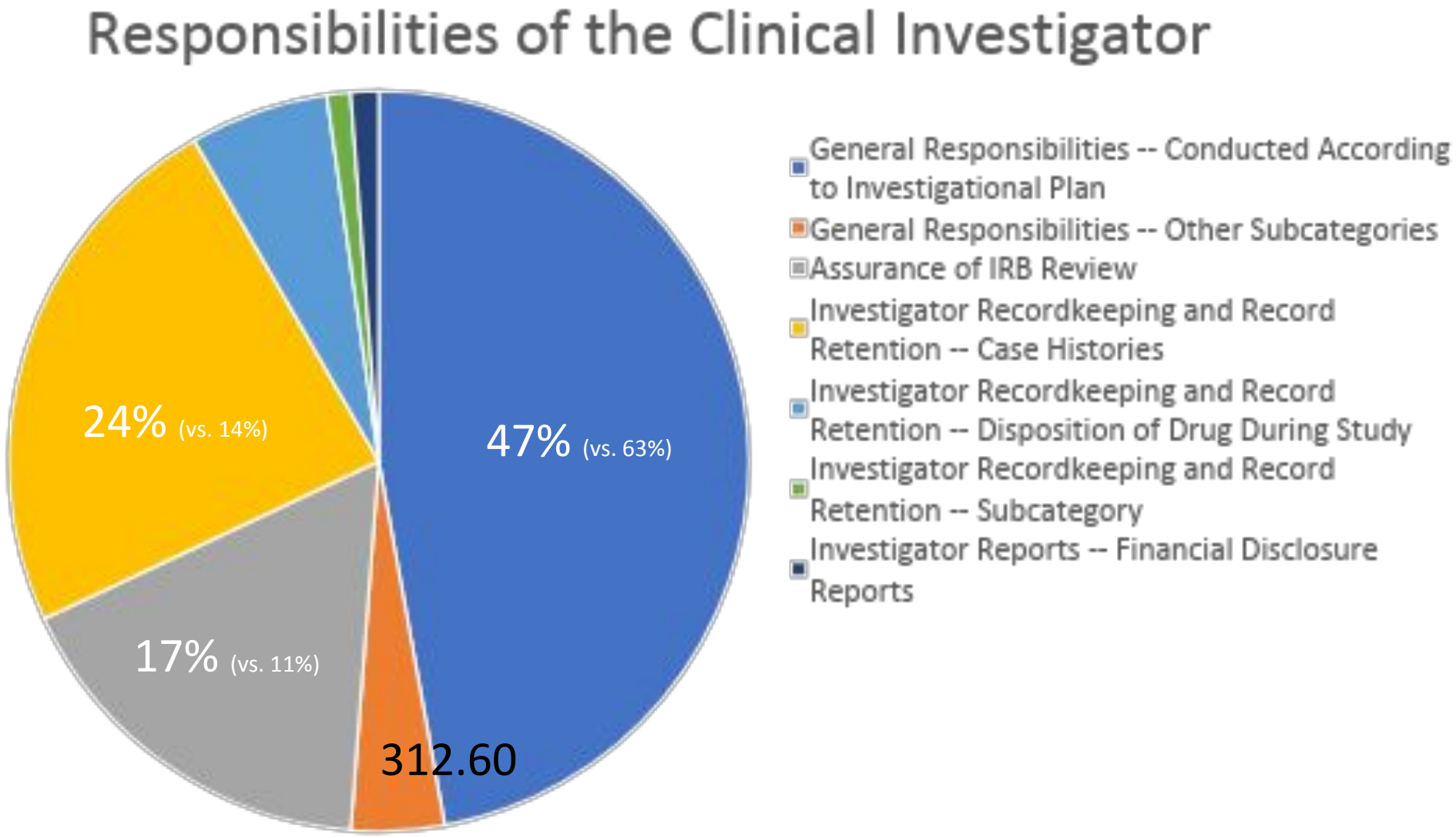
FDA 483 Analysis (n=1,213)



Again, wouldn't it be helpful to know what specific protocol violations are being found and noted under 312.60?

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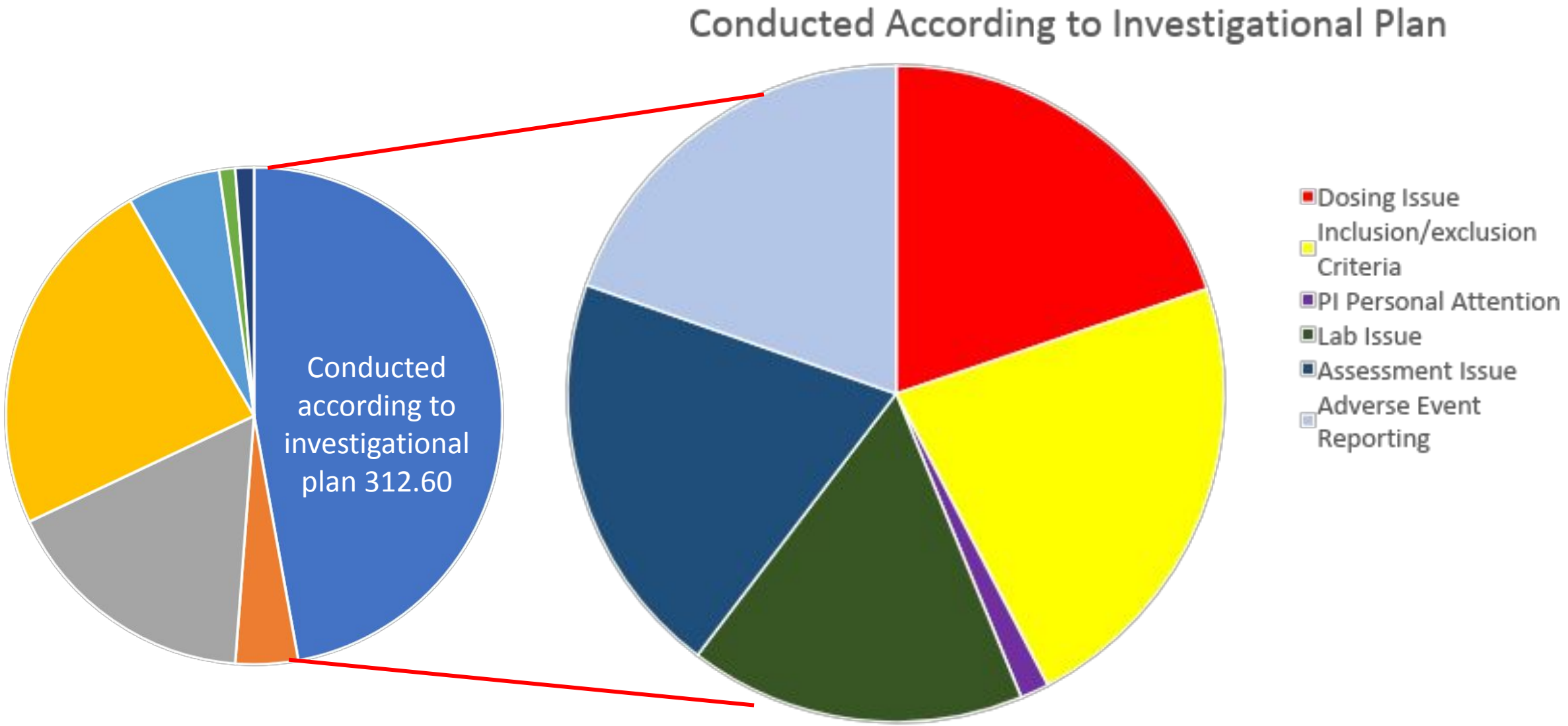
FDA 483 Analysis: *Not Conducted According to Plan (BETA)*(n=1,213)



These are areas we recommend focusing attention on in your operations to ensure there are no issues or gaps

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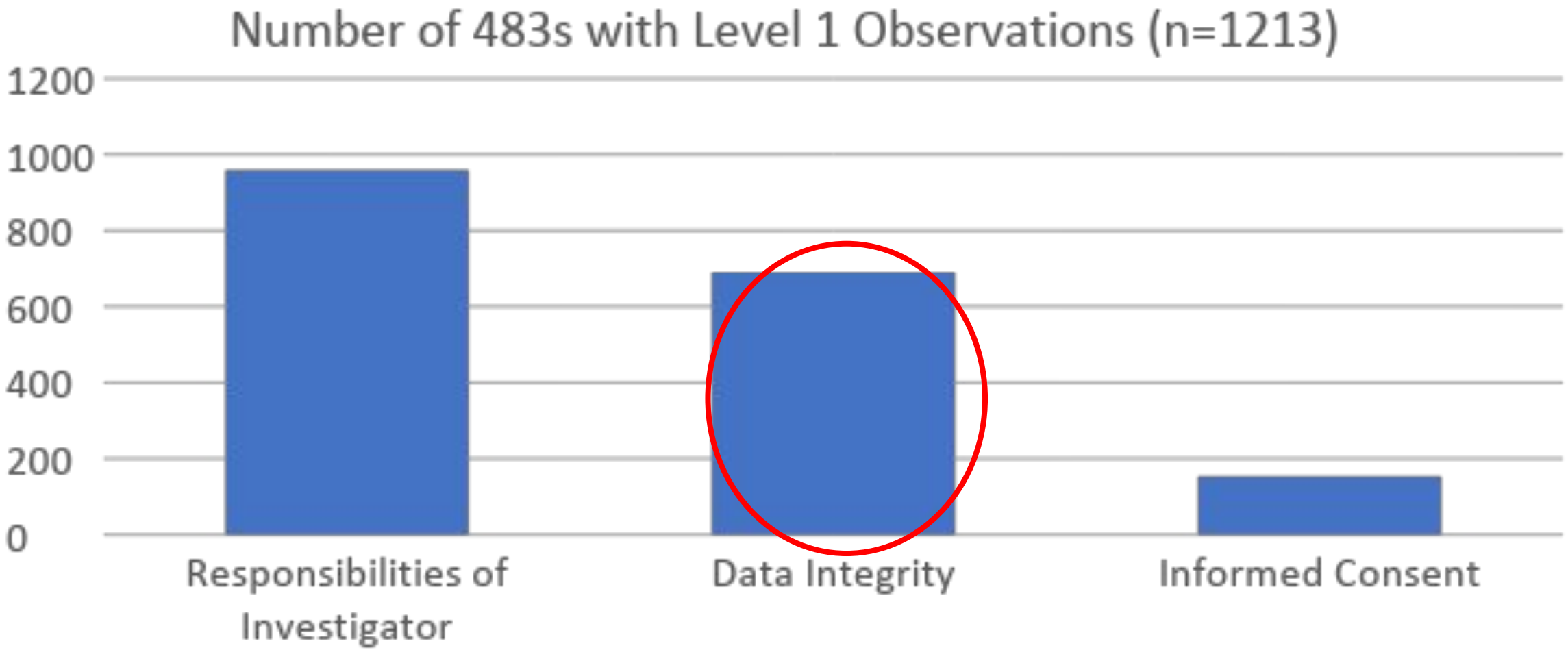
FDA 483 Analysis



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483 Analysis: Data Integrity: What is it and why is it important? ALCOA+

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
- Enduring
- Available

Decisions by investigator, agency, physicians, etc. depend in relying on the data

There have been major issues in data integrity in drug manufacturing inspections and in drug applications – ***rarely cited using "data integrity" unless particularly egregious; sometimes noted under case histories or documentation***

These have resulted in product recalls, new drug applications denied, and companies going out of business

When issues exist with the integrity of the data, all bets are off. These should be a bright red flag.

What do these issues look like?

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Data Integrity Examples Found in 483s

At least three subjects' records showed discrepancies between the source documents and Case Report Forms (CRFs)

… no source documentation was available

… the rest of the form is blank.

According to the eCRF audit trail, dated (b)(6), the entry states that the call was not made. However, the response was changed on the source document on (b)(6) to 'Yes' due to "entry error."

Subject (b)(6): Source record is blank… but was updated on (b)(6) with handwritten notes documenting that the calls took place on (b)(6). According to the eCRF audit trail, dated (b)(6), the entry states that the calls were not made. However, the response was changed on the source document on (b)(6) to 'Yes' due to "entry error."

What did our model find regarding possible data integrity issues in the 483s and in what form?

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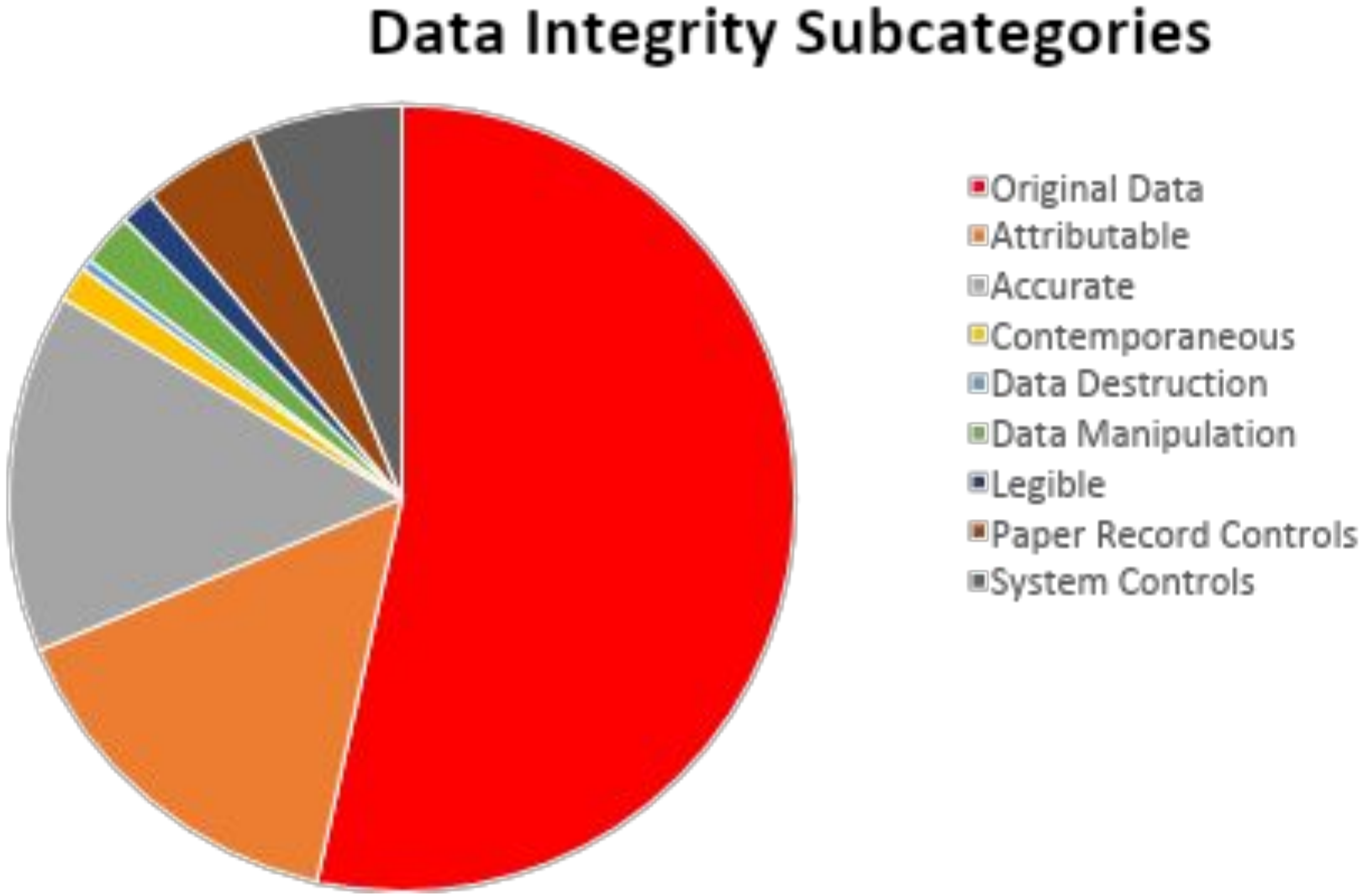
FDA 483 Analysis: Data Integrity Issues in Over Half of 483s ***(BETA)***



Over three-quarters of data integrity issues in 483 observations related to original data, attribution, or accuracy

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Data Integrity Example Language from 483 Observations: **Original Data**

- *source documents indicated...*
- *no documentation to support...*
- *no information to identify the subject anywhere on the source document*
- *original source diary indicated...*
- *diary entry on day 6 is a carbon entry from day 5...*

Can you trust this data? Can FDA use it to evaluate your clinical studies? Do you have these issues in your operations?

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Agenda

- Importance and challenges of human clinical studies
- Inspection landscape: deficiency statistics
- Data sources and evaluation using AI Tools
- What we can learn from US FDA CI Warning Letters
- A deeper dive into 483 data and some surprises
- Summary and Conclusions

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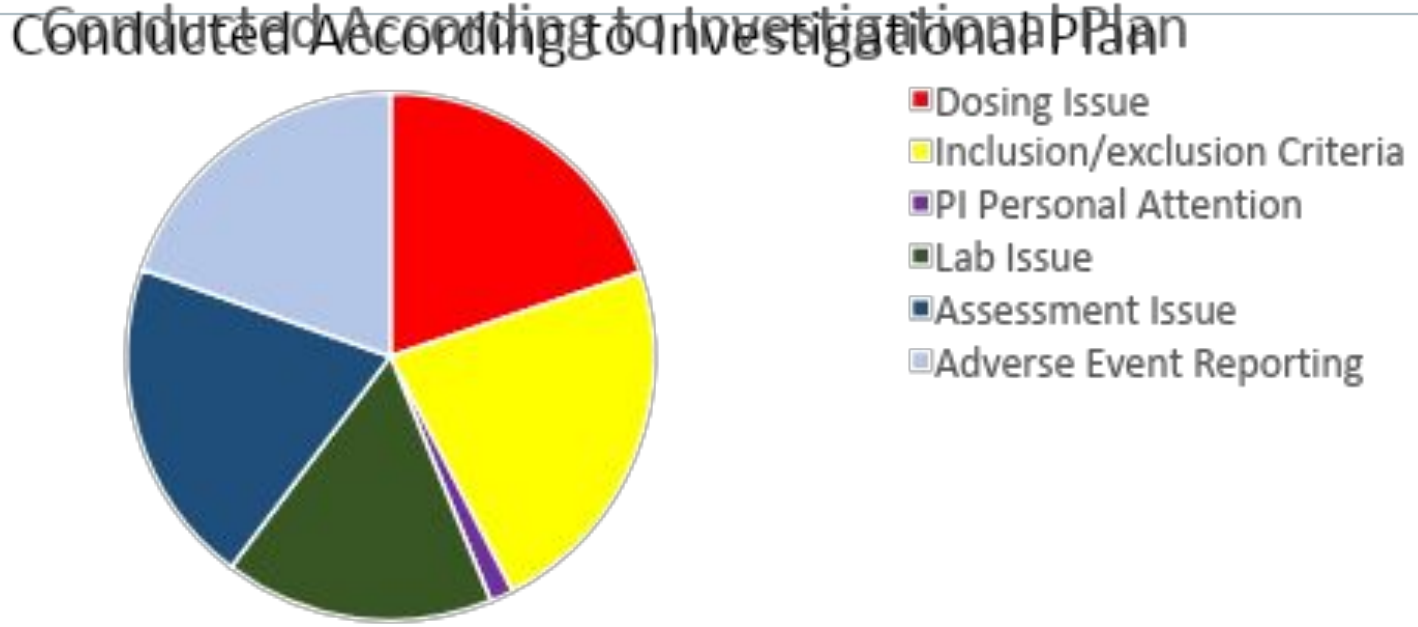
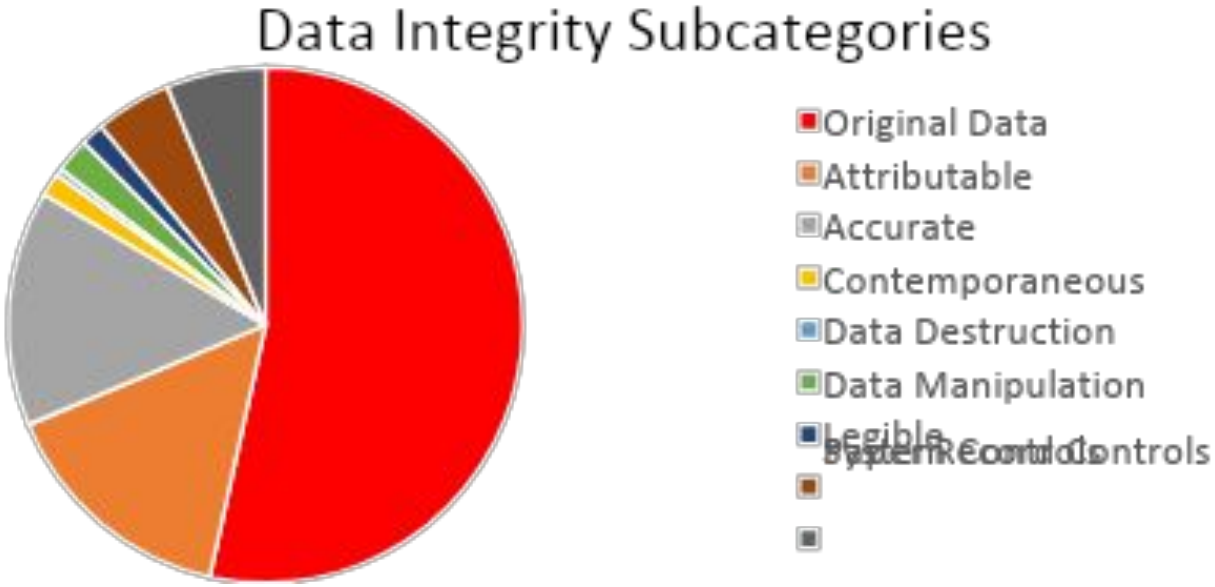
Summary and Conclusions

- Rich data sets can be analyzed and reveal critical insights when using the right tools
- Our models show what FDA is looking for and the deficiencies they are finding at an actionable level of detail.





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How Redica Systems Can Help

- ***Study startup and ongoing monitoring****: Full regulatory histories on GLP and GCP vendors*

- ***Strategic inspection preparation****: Keep current on inspection findings at your sites and others; look for trends in the data*

- ***Tactical inspection preparation****: Complete FDA investigator profiles – know what they look for when they show up*

- ***Regulatory and standards monitoring tool****: Keep up to date with GLPs, GCPs, GMPs, GMP for IMP, regulations and standards from the top 150 regulators and standards bodies*

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Thank You and Contact Information

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